Centers for Medicare & Medicaid Services (CMS) Public Agenda Payment and Coding Determinations for New Durable Medical Equipment

Wednesday, June 25, 2003
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

7:15 a.m. Arrival and registration

8:00 a.m. Welcome
Background and purpose of meeting – Cindy Hake, CMM

Meeting Format and Ground Rules – Dr. Bernice Harper, Office of Professional Relations

AGENDA ITEM # 1, Attachment #03.144
Request to establish a code for a postural car seat, Trade Name: Positioning Car Seat.

AGENDA ITEM # 2, Attachment # 03.100
Request to establish a code for an orthopedic car seat, Trade Name: Orthopedic Positioning Auto Safety Seat.

AGENDA ITEM # 3, Attachment # 03.112
Request to establish a code for a pedi-crib Trade Name: Pediatric Crib.

AGENDA ITEM # 4, Attachment # 03.91
Request to establish a code for a three-piece pediatric headrest, Trade Name: Southwest medical online pediatric three-piece headrest.

AGENDA ITEM # 5, Attachment # 03.103
Request to establish a code for a head support, Trade Name: Southwest Medical Inc. Support, Head.

AGENDA ITEM # 6, Attachment # 03.74
Request to establish a code for a transfer medical bed, Trade Name: Vivax Mobility System.

AGENDA ITEM # 7, Attachment # 03.88&03.101 (A&B)

A) Request to establish a code for an air pressure mattress with self adjusting valves, Trade Name: AtmosAir
B) Request to establish a code for specialized beds or mattresses, Trade Name: KinAir III.

AGENDA ITEM # 8, Attachment # 03.79&03.80 (A&B)

A) Request to establish a code for glucose monitoring device, Trade Name: Gluco Watch G2 Automatic Glucose Biographer.
B) Request to establish a code for a plastic sensor to be used with the Gluco Watch, Trade Name: Auto Sensors

AGENDA ITEM # 9, Attachment # 03.108

Request to establish a code for a blood glucose monitor, Trade Name: FreeStyle Tracker

AGENDA ITEM # 10, Attachment # 03.72

Request to establish a code for a humidification chamber, Trade Name: HC 325 and HC 345 Humidification Chamber.

AGENDA ITEM # 11, Attachment # 03.84

Request to establish a code for a high flow humidification system, Trade Name: Vapotherm.

AGENDA ITEM # 12, Attachment # 03.89

Request to establish a code for a data management accessory for CPAP, Trade Name: Encore PorSmart Card Technology.

AGENDA ITEM # 13, Attachment # 03.110

Request to establish a code for a non-continuous ventilator, Trade Name: REMstar Pro with C-Flex CPAP system.

AGENDA ITEM # 14, Attachment # 03.57

Request to establish a code for a lumbar passive motion device, Trade Name: LPM 100.

AGENDA ITEM # 15, Attachment # 03.69

Request to establish a code for a wearable, automatic defibrillator, Trade Name: Life Vest Wearable Cardioverter Defibrillator (WCD).

AGENDA ITEM # 16, Attachment # 03.71

Request to establish a code for a flow pump, Trade Name: Aircast Arterial Flow Pump 32-A.

AGENDA ITEM # 17, Attachment # 03.83

Request to establish a code for a pneumatic compression device, Trade Name: Art Assist.

AGENDA ITEM # 18, Attachment # 03.50

Request to establish a code for a low-pressure pulse, generator, Trade Name: Menniett Low Pressure Pulse Generator.

AGENDA ITEM # 19, Attachment # 03.109

Request to establish a code for an integrated electrode garment system, Trade Name: BioBelt, BioVest, BioSleeve, and Bio Unitard Integrated NMES/TENS Pain Management System.

AGENDA ITEM # 20, Attachment # 03.46
Request to establish a code for continuous cold therapy, Trade Name: DeRoyal Cryotherapy T 305 A.T.C.

AGENDA ITEM # 21, Attachment # 03.70
Request to establish a code for sleep apnea breathing device, Trade Name: Autoset Spirit auto-adjusting respiratory device.

5:00 p.m. ADJOURN

Guidelines for proceedings at CMS' Public Meetings for New DME are posted on the web at: www.cms.hhs.gov/medicare/hcpcs/default.asp

**** In the event that the National Security Alert is upgraded to Code Red for the date(s) of the Public Meeting(s), phone Jennifer Carver at 410-786-6610 or Cindy Hake at 410-786-3404 for a recorded message regarding the status of the DME Public meeting.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 01, Attachment # 03.144

Topic: Request to establish a code for a postural car seat, Trade Name: Positioning Car Seat.

Background/Discussion: Dianne L. Baum, of the Washington State, Department of Social and Health Services, has submitted a request to establish a code for a postural car seat, Trade Name: Positioning Car Seat. According to the requestor, positioning car seats are specifically designed for children/teens/adults who have special needs. All car seats provide support and promote proper seating. Accessories are available to allow for customization for specific positioning needs.

According to the requestor, this product has been available for over 10 years.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Establish the following "T" code:
T????-Therapeutic positioning seat for use in vehicles.

Payment: This item is not considered DME and would not be paid for under Medicare. However, a T code is recommended for Medicaid use.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 02, Attachment # 03.100

Topic: Request to establish a code for an orthopedic car seat, Trade Name: Orthopedic Positioning Auto Safety Seat.

Background/Discussion: Jane Wood of the State of South Carolina DHHS submitted a request to establish a code for an orthopedic car seat, Trade Name: Orthopedic Positioning Auto Safety Seat. According to the requestor, there are currently only local codes to describe this item. The orthopedic car seat is specifically designed to provide support and protection to children with special needs, while in moving vehicles. It keeps small or slender children positioned with full positioning pad sets. The padded head supports and 5-point harness are easily adjusted so that the seat grows with the child. This item fits many strollers.

This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation:

CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Establish the following "T" code:
T????-Therapeutic positioning seat for use in vehicles.

Payment: This item is not considered DME and would not be paid for under Medicare. However, a T code is recommended for Medicaid use.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 03, Attachment # 03.112

Topic: Request to establish a code for a pediatric crib, Trade Name: Pedi-Crib.

Background/Discussion: Jane Wood of the State of South Carolina DHHS has submitted a request to establish a code for a pediatric crib, Trade Name: Pedi-Crib. According to the requestor, Pedi-Crib provides a safe environment for children with disabilities to sleep and play independently. The crib can be completely enclosed to 1) reduce falls and injuries, 2) control wandering, 3) reduce pressure sores, loss of bone mass, and pneumonia, 4) promote quick recovery and muscle tone. It is used for children with neuromotor dysfunction, such as victims of stroke, head injury, seizures, mental retardation, and other disabilities.

This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Establish the following "E" code.

E???? Pediatric crib, hospital grade, fully enclosed.

Payment: Code E???? would fall under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase basis. The fee schedule amounts would be gap-filled by the DMERCs.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Meeting Agenda Item # 04, Attachment # 03.91

Topic: Request to establish a code for a three-piece head rest, Trade Name: Pediatric Three Piece Head Rest.

Background/Discussion: Jane Wood of the State of South Carolina DHHS has submitted a request to establish a code for a three-piece headrest, Trade Name: Pediatric Three Piece Head Rest. Currently, there are only local codes that describe this item. According to the requestor, Pediatric Three Piece Head Rest is a device that helps position and support the head in a neutral and proper alignment. It provides lateral and posterior support and will help prevent head and neck injuries due to poor head control and seizures. It is used in children with seizure disorders and motor skill development delay.

This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Establish the following "E" code:

E???? Wheelchair accessory, headrest, cushioned, prefabricated, including fixed mounting hardware, each.

Payment: Code E???? would fall under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase basis. The fee schedule amounts would be gap-filled by the DMERCs.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Meeting Agenda Item # 05, Attachment # 03.103

Topic: Request to establish a code for a support, head, Trade Name: Southwest Medical Inc. Support, Head.

Background/Discussion: Jane Wood of the State of South Carolina DHHS submitted a request to establish a code for a head support, Trade Name: Southwest Medical Inc. Support, Head. According to the requestor, this head support is a one-piece comfort sling device that enhances stability and easy transferring. It is used in children with neuromuscular disorder, musculoskeletal disorder, and spasticity control for postural control for sitting.

This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation:

CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use newly established "E" code:

E???? Wheelchair accessory, headrest, cushioned, prefabricated, including fixed mounting hardware, each.

Payment: Code E???? would fall under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase basis. The fee schedule amounts would be gap-filled by the DMERCs.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 06, Attachment # 03.74

Topic: Request to establish a code for a transfer medical bed, trade name: Vivax Mobility System.

Background/Discussion: Thomas Ellen of Vivax Medical Corporation submitted a request to establish a code for a transfer medical bed, trade name: Vivax Mobility System. According to the requestor, Vivax mobility system consists of a hospital bed, a patient conveyor sheet and apparatus (transfer bed), and a wheelchair with articulation to work along with the transfer bed. The transfer bed and the wheelchair work together to take a patient in a lying or prone position in bed, to a seated position in the wheelchair without any manual manipulation. The system also works in reverse to take a patient in a seated position in the wheelchair to a lying position in a bed. The system can handle patients weighing up to 600 pounds. In addition the transfer bed has all of the functions of standard hospital beds and can use any type of medical or therapeutic mattress.

According to the requestor, this product received an FDA 510(k) clearance in December 1987. This item is used 100% of the time in the patients' homes.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Not to establish a code due to low volume of documented use and use existing code E1399.

Payment: Claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced."

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 07, Attachments #03.88 & # 03.101

Topic: Request to establish a series of unique codes for pressure reducing support surfaces.

Background/Discussion: Susan Morris of KCI requested a code for an air pressure mattress with self-adjusting valves, Trade Names: AtmosAir 4000 and AtmosAir 9000; and a code for "specialized" bed and mattress systems. The requestor describes these products as non-electric powered pressure reducing mattress systems that use atmospheric pressure and gravity (air cylinders and pressure relief valves) to maximize weight displacement. Information was submitted for bed systems, including Trade Names: KinAir III and IV, TheraPulse, BariAir, Triadyne Proventa, Triadyne II and PediDyne. Information was also submitted for pressure reducing mattresses that utilize a pump, Trade Names: FIRST STEP Select, FIRST STEP Advantage, and FIRST STEP Select, HEAVY DUTY.

According to the requestor, these products have been on the market since 1999. They are class I devices, exempt by the FDA. The AtmosAir 4000 is used 81% of the time in hospitals, 16% of the time in nursing facilities, and 3% of the time in the home. The AtmosAir 9000 is used 90% of the time in the hospital, 8% of the time in nursing facilities, and 1% of the time in the patient's home. The bed systems are exempt from the FDA's requirement for pre-market notification.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendations to the HCPCS National Panel: Use the following existing codes.
(03.101) Use existing code E0193 "POWERED AIR FLOTATION BED (LOW AIR LOSS THERAPY)" for the KinAir III, KinAir IV, the TheraPulse, the BariAir, the Triadyne Proventa, the Triadyne II and the PediDyne.

(03.101) E0180 "PRESSURE PAD, ALTERNATING WITH PUMP" for the "FIRST STEP Select and the FIRST STEP Advantage.

(03.101) E0181 "PRESSURED PAD, ALTERNATING WITH PUMP, HEAVY DUTY for the FIRST STEP Select, Heavy Duty.

(03.88) E0186 "AIR PRESSURE MATTRESS" for the AtmosAir air pressure mattress.

Payment: (03.101)Codes E0180, E0181, and E0193 fall under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). If covered, payment would be made on a rental basis. The national, monthly rental, fee schedule ceiling for E0180 is currently $21.73 and the floor is $18.47. The national, monthly rental, fee schedule ceiling for E0181 is currently $24.08 and the floor is $20.47. The national, monthly rental, fee schedule ceiling for E0193 is currently $903.46 and the floor is $767.94
(03.88)Code E0186 falls under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). If covered, payment would be made on a rental basis. The national, monthly rental, fee schedule ceiling for E0186 is currently $20.30 and the floor is $17.26.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 08, Attachments # 03.79 & # 03.80

Topic: Request to establish a code for a GlucoWatch G2 Biographer, Trade Name: GlucoWatch®G2™Automatic Glucose Biographer, and a code for GlucoWatch Auto Sensors (intended for use with the GlucoWatch G2 Automatic Glucose Biographer)(03.80), Trade Name: Auto Sensors.

Background/Discussion: Kathy Francisco of The Pinnacle Health Group submitted a request to establish a code for a GlucoWatch G2 Biographer, Trade Name: GlucoWatch®G2™Automatic Glucose Biographer, and a request for a code for GlucoWatch Auto Sensors, Trade Name: Auto Sensors. According to the requestor, GlucoWatch ®G2™Automatic Glucose Biographer (GlucoWatch) is a non-invasive glucose monitoring device which detects trends and tracks patterns in glucose levels in adults and children with diabetes. It is intended for use as an adjunctive device to supplement information obtained from standard home glucose meters. It is used to detect and assess episodes of hyperglycemia and hypoglycemia in order to facilitate therapy adjustments. The device is worn like a watch on the forearm and obtains glucose noninvasively by reverse iontophoresis. An extremely low current extracts interstitial glucose through the skin. The GlucoWatch has two main parts: the GlucoWatch itself, which is the watch-like device worn on the forearm and the AutoSensor, which is the plastic part with gel discs that snaps into the GlucoWatch and adheres to the skin. It consists of two gel collection discs and an adhesive pad. The AutoSensor collects the glucose extracted through the patient's skin via an extremely low electric current emitted by the GlucoWatch. As the glucose molecules collect on the gel discs, they react with the enzyme glucose oxidase to form hydrogen peroxide. This reaction produces an electrochemical signal that is detected and measured by a biosensor inside the GlucoWatch. Each sensor provides up to 13 hours of readings and must be replaced each time the Biographer is worn.

According to the requestor, the devices were brought to market in April 2002. They are used 2% of the time in physician's offices, 1% of the time in freestanding ambulatory care clinics, 96% of the time in the patient's home by the patient, and 1% of the time in hospital outpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: For each request (the GlucoWatch and the AutoSensors), use existing code A9270 (non-covered item or service) for Medicare; and S1030 for other payers "continuous, non-invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)".

Payment: These items are not covered; therefore, no payment determination is necessary.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 09, Attachment # 03.108

Topic: Request to establish a code for a blood glucose monitor, trade name: FreeStyle® Tracker.

Background/Discussion: Jerry Stringham of Medical Technology Partners, Inc. submitted a request to establish a code for a blood glucose monitor, trade name: FreeStyle® Tracker. According to the requestor, FreeStyle consists of a glucose module, a personal data assistant and special analysis software. The module has a slot for insertion of a blood glucose test strip, electronics to evaluate the blood sample and an output to present other results. Personal data assistant receives inpute through the screen by a patient or directly from the module, and the software comes with an adaptor to enable transmission of data to a computer or health provider. PDA software tracks glucose values, insulin, carbohydrate counting, exercise, state of health, and medication. In addition, it can provide statistics with charts and graphs.

According to the requestor, this product has been on the market since June 2002. It received 510(k) clearance by the FDA. This item is used 15% of the time in physicians' offices and 85% of the time in the patients' homes.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code A9900, miscellaneous DME supply, accessory, and/or service component of another HCPCS code. This is a convenience item, not primarily medical in nature.

Payment: This item is not covered; therefore, no payment determination is necessary.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 PublicMeeting Agenda Item # 10, Attachment # 03.72

Topic: Request to establish a code for a humidification chamber, Trade Name: HC325 and HC345 Humidification Chamber.

Background/Discussion: Steve Moore of Fisher & Paykel Healthcare, Inc. submitted a request to establish a code for a humidification chamber, Trade Name: HC325 and HC345 Humidification Chamber. According to the requestor, the HC325 and HC345 chambers are used to hold distilled water to enable heated humidification in Positive pressure therapy. These chambers are mounted to the heater plate by a spring loaded latching system. Humidification chambers are then filled to the fill line and the appropriate patient delivery tubing is attached. le heated humidification in Positive pressure therapy. These chambers are mounted to the heater plate by a spring loaded latching system. Humidification chambers are then filled to the fill line and the appropriate patient delivery tubing is attached.

According to the requestor, this product was approved by the FDA in February 1995. This item is used 95% of the time in the patient's home and 5% of the time in inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel to establish the following "A" code:

A???? Replacement water chamber for humidifier, used with positive airway pressure device, each.

Payment: Code A???? would fall under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase basis. The fee schedule amounts would be gap-filled by the DMERCs.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 11, Attachment # 03.84

Topic: Request to establish a code for a high flow humidification systems and accessories, Trade Names: Vapotherm 2000i, Vapotherm DTPV9007, Vapotherm DTPV9007-CA2, Vapotherm DTPV9020, Vapotherm WR1200, Vapotherm VT01-A.

Background/Discussion: Bill Niland of Vapotherm, Inc. has submitted a request to establish a code for a high flow humidification systems and accessories, Trade Names: Vapotherm 2000i, Vapotherm DTPV9007, Vapotherm DTPV9007-CA2, Vapotherm DTPV9020, Vapotherm WR1200, Vapotherm VT01-A. According to the requestor, Vapotherm®*2000i* is the only device that can comfortably deliver breathing gas flows of up to 40 liters per minute directly to a nasal cannula, or other small-tube respiratory interfaces. The system consists of a base driver unit and a series of accessories for single patient use. The Vapotherm system is able to generate a high flow of warm and sterile vapor because of its membrane transfer technology that saturates a stream of air and/or oxygen. As a result, high flows can be administered easily without invasive techniques, eliminating masks, positive pressure ventilation, or other less desirable methods. The Vapotherm is used to treat a broad range of chronic lung diseases and airway inflammations.

According to the requestor, this item was brought to market in the first quarter of 2001. It received an FDA 510(k) clearance in August 2000. This item is used 10% of the time in the patient's home by the patient and 90% of the time in hospital inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code A9270, (non-covered item or service) for Medicare.

Payment: This item is not covered; therefore, no payment determination is necessary.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Meeting Agenda Item # 12, Attachment # 03.89

Topic: Request to establish a code for a data management accessory for positive airway pressure device, Trade Name: Encore®Pro SmartCard® Technology.

Background/Discussion: Beth Guevara of Respironics, Inc. and Krista Vihma of Lash Group Healthcare Consultants submitted a request to establish a code for a data management accessory for positive airway pressure device, Trade Name: Encore®Pro SmartCard® Technology. According to the requestor, Encore®Pro SmartCard® Technology is an accessory used with continuous positive airway pressure devices and bi-level respiratory assist devices. It is a removable data recorder that is installed into the side of a compatible positive airway pressure device. The patient compliance data recorded can be downloaded for review by the patient's physician or homecare provider through the use of Encore®Data Management Software. Once the data is downloaded, the data is displayed as a graphical and statistical analysis of the patient's usage patterns for use by the clinician and home care provider to assess compliance or to maintain a patient's therapeutic history.

According to the requestor, this item was brought to market in October 1999. This item is used 93% of the time in the patient's home by the patient, 1% of the time in nursing homes/SNF's, and 6% of the time in hospital inpatient facilities.

The addition of Encore® Pro SmartCard® Technology typically represents an additional cost.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code A9900. This product attaches to the CPAP and monitors compliance and the therapeutic history. It is included in the cost and payment of the predicate device, therefore, it is appropriately coded at A9900, miscellaneous DME supply, accessory, and/or service component of another HCPCS code.

Payment: Payment is included in the payment for the CPAP device (code E0601).

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 13, Attachment # 03.110

Topic: Request to establish a code for a ventilator, non-continuous, Trade Name: REMstar® Pro with C-Flex™ CPAP System.

Background/Discussion: Beth Guevara of Respironics, Inc. and Krista Vihma of Lash Group Healthcare Consultants have submitted a request for a ventilator, non-continuous, Trade Name: REMstar® Pro with C-Flex™ CPAP System. According to the requestor, REMstar ® Pro with C-Flex™ CPAP System is a microprocessor-controlled blower based continuous positive airway pressure device. It is a new technology that provides variable pressure relief during exhalation. By providing pressure relief at exhalation, it improves the comfort of the therapy, providing a more natural feeling for the patient. There are three settings that provide increased levels of pressure relief. The amount of pressure relief is determined by two parameters: patient's expiratory flow and the C-Flex setting selected by the patient. It is used with a breathing circuit that connects the device to the patient interface, typically a nasal or nasal-oral mask. The C-Flex is used in the treatment of adult Obstructive Sleep Apnea (OSA). The patient uses the system during all periods of sleep to prevent apneic episodes from occurring.

According to the requestor, this item was brought to market in September of 2002. Bioflex garments, assorted models were given 510(k) clearance in 1994. This item is used 93% of the time in the patient's home by the patient, 1% of the time in nursing homes/SNF's, and 6% of the time in hospital inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code K0532, respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device).

Payment: Code K0532 falls under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). Payment is made on a rental basis. The national, monthly rental fee schedule ceiling for K0532 is currently $256.60 and the floor is $218.11.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 14, Attachment # 03.57

Topic: Request to establish a code for a lumbar passive device, Trade Name: LPM 100.

Background/Discussion: Robert McIlwain of American Medical Devices, Inc. submitted a request to establish a code for a lumbar passive device, Trade Name: LPM 100. As described by Mr. McIlwain, the LPM 100 is a lumbar passive motion device used for patients who have acute/chronic low back pains or lumbar laminectomy. It works by periodically increasing the amount of motion to the upper range of restricted motion. By increasing range of motion, pain is decreased and patients are able to heal more quickly. After surgery, this motion is applied to the lumbar spine and is continued intermittently in the home under the supervision of an AMD Rehab Technician until the soft tissues have healed in a controlled manner. Range of motion is adjusted in accordance to protocol and patient tolerance. A variable speed control is provided to give a minimum of 2 cycles per minute and a maximum of 15 cycles per minute. This device can be used in the supine or prone position depending on the type of injury.

According to the requestor, this product has been on the market since 1991. The FDA cleared the product for marketing in March 1992, following a 510(k) premarket notification and an FDA determination that the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. This item is used 1% of the time in physicians' offices, 1% of the time in PT clinics and 98% of the time in the patients' home by the health care provider.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Not to establish a new code due to low volume of documented use. Use existing code E1399, Durable Medical Equipment, miscellaneous.

Payment: Claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced."

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 15, Attachment # 03.69

Topic: Request to establish a code for a wearable, automatic defibrillator, external, Trade Name: LifeVest™Wearable Cardioverter Defibrillator (WCD®System)

Background/Discussion: Krista Vihma submitted a request to establish a code for a wearable automatic external defibrillator Trade Name: LifeVest™Wearable Cardioverter Defibrillator (WCD®System). According to Ms. Vihma the LifeVest™ is worn outside the body, rather than implanted in the chest. The patient wears the system continuously, and does not require bystander intervention to treat an arrhythmia, as it is programmed to deliver shock in the event of a life-threatening arrhythmia. The device monitors of ECG information, storing data for later review by the treating physician. In addition to automatic ECG recording, the patient may electively cause an ECG record to be captured if he/she experiences suspected cardiac symptoms. Physicians can access the ECG data through a secure web-based data storage and retrieval system known as WCDNET®. The LifeVest is used for patients at risk for sudden cardiac arrest, who are not candidates for or an implanted cardiac defibrillator.

According to the requestor, this product was brought to market on January 1, 2002. This item is used 100% of the time in the home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use newly established codes K0606 (AUTOMATIC EXTERNAL DEFIBRILLATOR, WITH INTEGRATED ELECTROCARDIOGRAM ANALYSIS, GARMET TYPE), K0607 (REPLACEMENT BATTERY FOR AUTOMATED EXTERNAL DEFIBRILLATOR, EACH), and K0609 (REPLACEMENT ELECTRODES FOR USE WITH AUTOMATED EXTERNAL DEFIBRILLATOR, EACH).

Payment: Code K0606 has been classified under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). If covered, payment would be made on a rental basis. CMS and the DMERCs are currently gathering pricing information for use in establishing the fee schedule amounts for this code. We do not expect that a fee schedule will be established for this code before October 1, 2003. In the interim the DMERCs will make payment based on their individual consideration of each claim.

Code K0607 has been classified under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase or rental basis. The national, purchase fee schedule ceiling to be implemented on July 1, 2003, for K0607 will be $194.23 and the floor will be $165.10. The national, monthly rental, fee schedule ceiling to be implemented on July 1, 2003, for K0607 will be $19.43 and the floor will be $16.52. Code K0609 has been classified under the DME fee schedule payment category for DME supplies (pricing indicator of 34 in the HCPCS). If covered, payment would be made on a purchase basis. The national, purchase fee schedule ceiling to be implemented on July 1, 2003, for K0609 will be $806.09 and the floor will be $685.18.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 16, Attachment # 03.71

Topic: Request to establish a code for an intermittent pneumatic compression device, Trade Name: Aircast Arterial Flow Pump 32-A.

Background/Discussion: Gina Grage of the Mayo Clinic Store submitted a request to establish a code for an intermittent pneumatic compression device, Trade Name: Aircast Arterial Flow Pump 32-A. According to the requestor, this device has been shown to salvage limbs in 40% of cases where the patient was in need of an amputation due to poor circulation or chronic non-healing wounds. It augments arterial flow and microcirculation with pulsating compression of the calf. The patient puts a cuff around their calf, and attaches the cuff to the pump. When the pump is turned on, compression is rapid, graduated and sequential, settling to 95mmHg. After 2 seconds, the cuff deflates. This sequence is repeated every 20 minutes. Patients are advised to use this device at least 3 hours per day over the course of 3-5 months.

According to the requestor, this item was brought to market in 1997. This item is used 95% of the time in the patient's home by the patient and 5% of the time in nursing homes and SNF's.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing Code E0651 pneumatic compressor, segmental home model without calibrated gradient pressure for the compressor, and use E1399 for the cuff.

Payment: Code E0651 falls under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). Payment is made on a purchase or rental basis. The national, purchase fee schedule ceiling for E0651 is currently $918.42 and the floor is $780.66. The national, monthly rental, fee schedule ceiling for E0651 is currently $93.82 and the floor is $79.75.

Claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced."

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Meeting Agenda Item # 17, Attachment # 03.83

Topic: Request to establish a code for a pneumatic compression device, Trade Name: ArtAssist.

Background/Discussion: Ed Arkans of ACI Medical, Inc. submitted a request to establish a code for pneumatic compression device, Trade Name: ArtAssist®. According to the requestor, ArtAssist is used for patients with peripheral arterial disease (PAD), diabetic and non-diabetic arteriopathic foot and leg ulcers, after bypass surgery, intermittent claudication and rest pain. ArtAssist applies rapid, high-pressure, foot and calf, pneumatic compression to the lower extremities to increase arterial blood flow. This device is non-invasive, non-surgical and non-pharmaceutical. ArtAssist is the only external pneumatic compression device optimized for increasing arterial blood flow. It is shown to increase patient's blood flow in the popliteal artery and at the tissue level. There are three mechanisms by which ArtAssist improves blood flow: rapidly inflating foot and ankle bladders, inflating calf bladders, and compressing tissues below the knee. Arterial pressure is unchanged and the increased arterial-venous pressure gradient results in greater arterial inflow. The ArtAssist consists of a controller with electrical cord, tubing set (one per limb) and compression cuff(s) (one per limb).

According to the requestor, this product has been on the market since February 1996. It received 510(k) clearance from the FDA in February, 1996. This item is used 83% of the time in the patients' home, 3% of the time in nursing facilities, 7% of the time in inpatient facilities, and 7% of the time in other.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code E0651 "pneumatic compressor, segmental home model without calibrated gradient pressure" for the compressor, and E1399 for the cuff.

Payment: Code E0651 falls under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). Payment is made on a purchase or rental basis. The national, purchase fee schedule ceiling for E0651 is currently $918.42 and the floor is $780.66. The national, monthly rental, fee schedule ceiling for E0651 is currently $93.82 and the floor is $79.75.

Claims for items billed using code E1399 (DM E, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced".

ALPHA-NUMERIC HCPCS REQUEST

June 25, Public Meeting Agenda Item # 18, Attachment # 03.50

Topic: Request to establish a code for Meniett Low-Pressure Pulse Generator, Trade Name: Meniett 20.

Background/Discussion: John Caserta of Medtronic Xomed submitted a request to establish a code for Meniett Low-Pressure Pulse Generator, Trade Name: Meniett 20. According to Mr. Caserta, the Meniett Low-Pressure Pulse Generator is used for the symptomatic treatment of Meniere's Disease. This is achieved by applying low frequency, low amplitude pressure pulses to the middle ear. Inner ear endolymphatic fluids are assumed to be evacuated from the cochlea, relieving the patient of the symptoms associated with the disease. The treatment consists of two phases: myringotomy and application of pressure pulses to the middle ear. Treatment is continued for as long as the patient is in a period of attacks of vertigo. The device is an electronically controlled membrane pump that generates dynamic pressure, it consists of a pump house, electronic hardware, software, and encapsulation.

According to the requestor, this product was cleared for marketing the FDA in December 1999 following a 510(k) premarket notification, and an FDA finding of substantial equivalence of the device to a legally marketed predicate device. This item is used 100% of the time in the home by patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Establish the following "E" code for the pulse generator system, and establish an "A" code for a replacement battery:

E???? – PULSE GENERATOR SYSTEM FOR THE TYMPANIC TREATMENT OF INNER EAR ENDOLYMPHATIC FLUID

A???? – REPLACEMENT BATTERY FOR PATIENT-OWNED EAR PULSE GENERATOR, EACH

Payment: Code E???? would fall under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). If covered, payment would be made on a rental basis. The fee schedule amounts would be gap-filled by the DMERCs.

Code A???? would fall under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). If covered, payment would be made on a purchase basis. The fee schedule amounts would be gap-filled by the DMERCs.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 19, Attachment # 03.109

Topic: Request to establish one or more codes, preferably L-codes, for pain management systems.

Background/Discussion: Philip Muccio, CPO of Bioflex Electromedicine, Inc. has submitted a request to establish one or more codes, preferably L-codes, to describe the following pain management systems:

A. Integrated NMES/TENS Pain Evaluation
B. BioBelt Integrated NMES/TENS Pain Management System
C. BioVest Integrated NMES/TENS Pain Management System
D. BioUnitard Integrated NMES/TENS Pain Management System
E. BioSleeve Integrated NMES/TENS Pain Management System
F. BioShort Integrated NMES/TENS Pain Management System
G. BioCollar Integrated NMES/TENS Pain Management System

The code E0731 that was recommended does not describe the professional time and care that is involved in the evaluation of the patient nor the professional care that is necessary to design, fabricate, modify and otherwise fit a customized electrode garment. According to the requestor, Bioflex Integrated NMES/TENS Pain Management System is a program of evaluation, determination of appropriateness/successful outcome, measuring, fitting and implementation of the Bioflex System, including two customized garment integrating electrodes, a Neuromuscular Stimulator or TENS or Combined NMES/TENS, training, follow-up, and finally modifications and repairs to assure wearability and suitability for long-term successful use of the product. It is used alone or in combination with other pain treatments to obtain maximum pain relief and maximum rehabilitation for restoration of function and return to work. It is used to alleviate pain that is usually of a chronic or long-term nature.

According to the requestor, this item was brought to market in 1995. This item is used 70% of the time in the patient's home by a health care provider and 30% of the time in a prosthetist's facility.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code E0731 "form fitting conductive garment for delivery of TENS or NMES" for the garments. Independently pursue the AMA via a separate application for consideration of a CPT code for the service component,

Payment: Code E0731 falls under the DME fee schedule payment category for inexpensive or routinely purchased items (pricing indicator of 32 in the HCPCS). Payment is made on a purchase basis. The national, purchase fee schedule ceiling for E0731 is currently $356.69 and the floor is $303.19.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 20 Attachment #03.46

Topic: Request to establish a code for continuous cold therapy, trade name: DeRoyal Cryotherapy T 305 A.T.C.

Background/Discussion: On behalf of DeRoyal Industries, Inc. Jim Pior submitted a request to establish a code for continuous cold therapy, trade name: DeRoyal Cryotherapy T 305 A.T.C. As described by Mr. Pior, DeRoyal Cryotherapy is a motorized cold therapy system with advanced technology temperature control. The A.T.C. is set at 45 degrees F for optimum heat reduction and avoidance of contraindications. The cryotherapy base is low profile and portable for transport. DeRoyal cryotherapy regulates the water temperature at the treatment site allowing hours of continuous therapy while circumventing exposure risks. In doing so, cryotherapy alleviates pain and swelling.

According to the requetor, this product has been on the market since January 2001. The FDA classified it under sec. 890.5720, water circulating hot or cold "water pack". This item is used 5% of the time in physician's offices, 5% of the time in the patient's home by the healthcare provider, 15% of the time in nursing facilities, 50% of the time in hospital inpatient facilities, and 25% of the time in hospital outpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code E0218, "water circulating cold pad with pump".

Payment: The DMERCs have decided that items falling under the E0218 category are not covered. Therefore, Medicare currently makes no payment for items in this category.

ALPHA-NUMERIC HCPCS REQUEST

June 25, 2003 Public Meeting Agenda Item # 21, Attachment # 03.70

Topic: Request to establish a code for a self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit.

Background/Discussion: Ron Richard of ResMed submitted a request to establish a code for a self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit. According to the requestor, the AutoSet is a flow-based auto-adjusting device used in the treatment of obstructive sleep apnea. The auto-adjusting respiratory device mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This mode of action is important because the device responds to flow limitation, snoring, hypopnea, or complete obstruction. As it responds in a proactive vs. reactive fashion, it senses changes in flow and adjusts the pressure.

According the requestor, this product has been on the market since July 2002 with a sale of 18,000 units in the six months prior to submitting the request. This item is used 90% of the time in the patients' homes and 10% of the time in inpatient facilities. In April 2002, the FDA responded to ResMed's 510(k) pre-market notification with a determination that this device is substantially equivalent to legally marketed predicate devices.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: Use existing code E0601 CONTINUOUS AIRWAY PRESSURE (CPAP) DEVICE, because this product is another form of CPAP.

Payment: Code E0601 falls under the DME fee schedule payment category for capped rental items (pricing indicator of 36 in the HCPCS). If covered, payment would by made on a rental basis. The national, monthly rental, fee schedule ceiling for E0601 is currently $111.71 and the floor is $94.95.